HEART VALVE DISEASE POLICY TASK FORCE

July 13, 2026

Administrator Mehmet Oz
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Oz,

As members of the Heart Valve Disease Policy Task Force, a national group of 30 leaders including clinician and patient advocates, we appreciate the opportunity to comment on the National Coverage Decision (NCD) proposed decision memo for Transcatheter Aortic Valve Replacement (TAVR).

We commend CMS for proposing significant updates that reflect the maturity of TAVR's evidence base and the evolution of real-world clinical practice. We strongly support many elements of the proposal, including:

- Providing national coverage for symptomatic severe aortic stenosis (AS) without Coverage with Evidence Development (CED);
- Eliminating facility volume requirements;
- Clarifying operator volume requirements;
- Streamlining patient evaluation requirements;
- Providing greater flexibility regarding Heart Team participation during TAVR procedures.

These changes represent important steps toward reducing barriers to care and improving access for Medicare beneficiaries with AS, a progressive and life-threatening condition.

We are particularly encouraged by CMS's proposal to sunset CED for symptomatic severe AS. The evidence supporting TAVR has matured substantially over the past decade, and the procedure is firmly established as a standard-of-care treatment.[1] As TAVR has become widely and safely adopted across diverse patient populations, continued CED no longer reflects the realities of contemporary practice. Eliminating CED appropriately aligns Medicare policy with current clinical evidence and will reduce administrative burdens that can delay care and limit patient access.

[1] Carroll, J. D., Mack, M. J., Vemulapalli, S., Herrmann, H. C., Gleason, T. G., Hanzel, G., … Bavaria, J. E. (2020). STS-ACC TVT Registry of transcatheter aortic valve replacement. *Journal of the American College of Cardiology, 76*(21), 2492–2516. https://doi.org/10.1016/j.jacc.2020.09.595

We also strongly support the removal of facility volume requirements. Expanding the number of hospitals able to offer TAVR can help improve geographic access to care, particularly for patients in rural, underserved, and socioeconomically disadvantaged communities. Evidence shows that patients living in low-population-density areas face disproportionate barriers to accessing TAVR, and that increasing the number of hospitals offering the procedure significantly reduces geographic access inequality. [2] Access to life-saving therapies should not be determined by a patient's proximity to a high-volume center when quality care can be delivered closer to home.

We also appreciate CMS's proposal to reduce operator volume requirements, which meaningfully modernizes the NCD and supports broader patient access to TAVR while maintaining a strong emphasis on quality and outcomes. By moving from legacy surgical metrics to standards based on recent transcatheter valve experience, CMS focuses operator expectations on the skills most associated with safe, high-quality TAVR performance. This update also removes structural barriers that have disproportionately affected emerging and underserved programs, helping ensure that capable operators can meet standards through active engagement in transcatheter valve care rather than historical surgical caseloads.

We further support CMS's proposal to modernize the patient evaluation process by allowing greater flexibility in how patients are assessed for TAVR. Under the proposed NCD, the longstanding requirement that both a cardiac surgeon and an interventional cardiologist conduct separate in-person evaluations would be replaced with a more streamlined approach: a single in-person evaluation by either specialist, supplemented by remote review of medical records for the second assessment. This update reflects contemporary clinical practice, reduces unnecessary burdens on patients, particularly those with mobility limitations or who live far from specialty centers, and preserves the rigor of multidisciplinary decision-making. Recent analyses also show that mandated specialist visits and imaging requirements are major contributors to treatment delays, independent of patient risk.[3] By enabling initial screening to occur remotely while still ensuring an in-person evaluation by a qualified specialist, CMS appropriately balances patient access, safety and efficiency.

While we appreciate CMS's efforts to modernize the NCD, we remain concerned that the proposed policy continues to require CED for patients with asymptomatic severe AS. We are encouraged that CMS recognizes this patient population within the NCD; however, requiring participation in a CMS-approved study may continue to create barriers to timely treatment.

Emerging evidence suggests that earlier intervention in appropriately selected patients with asymptomatic severe AS may prevent irreversible cardiac damage, reduce downstream

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[2] Bergman, A., David, G., Nathan, A., Giri, J., Ryan, M., Chikermane, S., Thompson, C., Clancy, S., & Gunnarsson, C. (2024). Measuring hospital inpatient Procedure Access Inequality in the United States. *Health Affairs Scholar*, *2*(11). https://doi.org/10.1093/haschl/qxae142

[3] Stinis, C., Tunis, S., Lauck, S., Gupta, A., Murphy, S., Chikermane, S., Clancy, S., & Russo, M. (2025). Impact of pre-procedural requirements on time to aortic valve replacement: Transcatheter AVR vs surgical AVR. *American Heart Journal Plus: Cardiology Research and Practice*, *61*, 100698. https://doi.org/10.1016/j.ahjo.2025.100698

morbidity, and improve long-term outcomes.[4] Coverage policies that rely on symptom onset alone risk delaying care until disease progression has already occurred. As additional evidence becomes available, we encourage CMS to establish a pathway toward broader national coverage for asymptomatic severe AS and ensure that patients do not experience unnecessary delays in receiving evidence-based treatment.

Thank you for the opportunity to provide these comments. We appreciate CMS's commitment to modernizing coverage policy and look forward to continued collaboration to improve outcomes for patients with aortic stenosis.

Sincerely,

The Heart Valve Disease Policy Task Force

Alliance for Aging Research

Alliance for Patient Access

American Society of Echocardiography

Conquering CHD

Heart Valve Voice US

Hypertrophic Cardiomyopathy Association

The Mended Hearts, Inc.

National Hispanic Health Foundation

Partnership to Advance Cardiovascular Health

Preventive Cardiovascular Nurses Association

RetireSafe

[4] Philippe Généreux, Schwartz, A., J. Bradley Oldemeyer, Philippe Pibarot, Cohen, D. J., Blanke, P., Lindman, B. R., Vasilis Babaliaros, Fearon, W. F., Daniels, D. V., Chhatriwalla, A. K., Kavinsky, C., Gada, H., Shah, P., Szerlip, M., Dahle, T., Goel, K., O'Neill, W., Sheth, T., & Davidson, C. J. (2024). Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis. *New England Journal of Medicine*. https://doi.org/10.1056/nejmoa2405880